

This listing of claims will replace all prior versions, and listings, of the claims in the application:

Listing of Claims:

Claim 1. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog thereof~~, and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-cyclodextrin.

Claim 2. (Currently Amended) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises a complex or solution of the therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog thereof~~, and the pharmaceutically acceptable solubilizing carrier molecule.

Claims 3-5. (Cancelled)

Claim 6. (Previously Presented) The pharmaceutical composition of claim 1, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

Claims 7-8. (Cancelled)

Claim 9. (Currently Amended) ~~The pharmaceutical composition of claim 1, A~~ pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-cyclodextrin and wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claim 10. (Cancelled)

Claim 11. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog thereof~~, and a pharmaceutically

acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-cyclodextrin, which when diluted with an aqueous solution for parenteral administration, remains soluble in the aqueous solution.

Claim 12. (Currently Amended) The pharmaceutical composition of claim 11, wherein the therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog thereof~~, is complexed with the pharmaceutically acceptable solubilizing carrier molecule.

Claims 13-14. (Cancelled).

Claim 15. (Previously Presented) The pharmaceutical composition of claim 11, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

Claim 16-17. (Cancelled).

Claim 18. (Currently Amended) ~~The pharmaceutical composition of claim 11,~~ A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-cyclodextrin, which when diluted with an aqueous solution for parenteral administration, remains soluble in the aqueous solution and wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claim 19. (Original) The pharmaceutical composition of claim 12, wherein the complex comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

Claim 20. (Cancelled).

Claim 21. (Currently Amended) A formulation comprising a therapeutically effective amount of comprising Beta-lapachone, ~~or a derivative or analog thereof~~, and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-

cyclodextrin, wherein the formulation can be freeze-dried and when subsequently reconstituted in aqueous solution is soluble.

Claim 22. (Currently Amended) The formulation of claim 21, wherein the Beta-lapachone, ~~or a derivative or analog thereof~~ is complexed with the pharmaceutically acceptable solubilizing carrier molecule.

Claims 23-24. (Cancelled).

Claim 25. (Previously Presented) The formulation of claim 21, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

Claims 26-27. (Cancelled).

Claim 28. (Currently Amended) ~~The formulation of claim 21,~~ A formulation comprising a therapeutically effective amount of comprising Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-cyclodextrin, wherein the formulation can be freeze-dried and when subsequently reconstituted in aqueous solution is soluble and wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claim 29. (Cancelled).

Claim 30. (Currently Amended) A kit for the treatment of a mammalian cancer comprising at least one vial containing Beta-lapachone, ~~or a derivative or analog thereof~~, according to any one of claims 1, 11 or 21.

Claim 31. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog thereof~~, and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-cyclodextrin, and further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

Claim 32. (Currently Amended) The pharmaceutical composition of claim 31, wherein the composition comprises a complex or solution of the therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog thereof~~, and the pharmaceutically acceptable solubilizing carrier molecule, and further comprises the second anticancer agent and a pharmaceutically acceptable carrier.

Claim 33. (Original) The pharmaceutical composition of claims 31 or 32, wherein the second anticancer agent is a taxane derivative.

Claim 34. (Original) The pharmaceutical composition of claim 33, wherein the taxane derivative is paclitaxel.

Claim 35. (Cancelled).

Claim 36. (Currently Amended) The pharmaceutical composition of claim 31, wherein the therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog thereof~~, and the pharmaceutically acceptable solubilizing carrier molecule is admixed with the second anticancer agent and the pharmaceutically acceptable carrier and contained in a single vial.

Claim 37. (Currently Amended) The pharmaceutical composition of claim 31, wherein the therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog thereof~~, and the pharmaceutically acceptable solubilizing carrier molecule is contained in a first vial, and the second anticancer agent and the pharmaceutically acceptable carrier are contained in a second vial.

Claims 38-39. (Cancelled).

Claim 40. (Previously Presented) The pharmaceutical composition of claim 31, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

Claims 41-42. (Cancelled).

Claim 43. (Currently Amended) ~~The pharmaceutical composition of claim 31, A~~
pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone
and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier
molecule is a beta-cyclodextrin, and further comprising a second anticancer agent and a
pharmaceutically acceptable carrier and wherein the concentration of Beta-lapachone in solution
is at least 1 mg/ml.

Claim 44. (Cancelled).

Claim 45. (Currently Amended) A kit for the treatment of a mammalian tumor comprising
one or more vials containing a therapeutically effective amount of Beta-lapachone, ~~or a~~
~~derivative or analog thereof,~~ and a pharmaceutically acceptable solubilizing carrier molecule,
wherein said solubilizing carrier molecule is a beta-cyclodextrin and further comprising, within
the same vial or a separate vial, a second anticancer agent.

Claim 46. (Currently Amended) The kit of claim 45, wherein the one or more vials contain a
complex of the therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog~~
~~thereof,~~ and the pharmaceutically acceptable solubilizing carrier molecule and further
comprising, within in the same vial or a separate vial, the second anticancer agent.

Claim 47. (Original) The kit of claims 45 or 46, wherein the second anticancer agent is a
taxane derivative.

Claim 48. (Original) The kit of claim 47, wherein the taxane derivative is paclitaxel.

Claims 49-50. (Cancelled).

Claim 51. (Previously Presented) The kit of claim 45, wherein the beta-cyclodextrin is
hydroxypropyl-beta-cyclodextrin.

Claims 52-53. (Cancelled).

Claim 54. (Currently Amended) ~~The kit of claims 45 or 46,~~ A kit for the treatment of a mammalian tumor comprising one or more vials containing a therapeutically effective amount of Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-cyclodextrin and, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml, and further comprising, within the same vial or a separate vial, a second anticancer agent.

Claims 55-179 (Cancelled).

Claim 180. (Currently Amended) A sterile injectable pharmaceutical composition for intravenous administration comprising a complex of a therapeutically effective amount of Beta-lapachone, ~~or a derivative or analog thereof,~~ and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-cyclodextrin.

Claim 181. (Cancelled)

Claim 182. (Previously Presented) The sterile injectable pharmaceutical composition of claim 180, wherein the pharmaceutically acceptable solubilizing carrier molecule is hydroxypropyl-beta-cyclodextrin.

Claim 183. (Original) The sterile injectable pharmaceutical composition of claim 180, further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

Claim 184. (Original) The sterile injectable pharmaceutical composition of claim 183, wherein the second anticancer agent is a taxane derivative.

Claim 185. (Original) The sterile injectable pharmaceutical composition of claim 184, wherein the taxane derivative is paclitaxel.

Claim 186. (Currently Amended) ~~The sterile injectable pharmaceutical composition of claim 180,~~ A sterile injectable pharmaceutical composition for intravenous administration comprising a

complex of a therapeutically effective amount of Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is a beta-cyclodextrin and wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claims 187-209. (Cancelled).